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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* RICHARD J. GREFF

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Appeal 2011-007510
Application 10/068,812
Technology Center 1600

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Before ERIC GRIMES, MELANIE L. McCOLLUM, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

## DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to cross-linked gelatin compositions. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

## STATEMENT OF THE CASE

The Specification discloses that "[c]ross-linked gelatin, often in the form of gelatin foam, gelatin film or gelatin sponges, has been used as a

hemostatic agent … to pack wounds, absorb blood and stop bleeding" (Spec. 3:14-16).

Claims 22-33 and 42 are on appeal. Claim 22 is representative and reads as follows:

22. A biocompatible, hemostatic, cross-linked gelatin composition comprising:
a preformed cross-linked gelatin sponge; and
a wetting agent;
wherein the wetting agent decreases hydration time of the gelatin sponge and the wetting agent is soluble in a non-aqueous solvent;
wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent.

The Specification discloses that suitable wetting agents "include, for example, sodium lauryl sulfate, Pluronic F-68, Pluronic F-38, Pluronic P-105, Pluronic-10R5, Tween 20, Tween 60, Tween 85, Brij 35, Brij 78, Myrj 52, PEG 600, glycerin and the like" (Spec. 12:1-4).

*Issue*

The Examiner has rejected claims 22-25, 27-30, 32, 33, and 42 under 35 U.S.C. § 102(b) as anticipated by Pawelchak.[1] The Examiner has also rejected claims 26 and 31 under 35 U.S.C. § 103(a): claim 26 in view of Pawelchak and Yasushi;[2] and claim 31 in view of Pawelchak and Song.[3] Because the same issue is dispositive for all three of these rejections, we will consider them together.

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[1] Pawelchak et al., US 4,292,972, Oct. 6, 1981
[2] Yasushi et al., JP 02-182259, July 16, 1990
[3] Song et al., EP 568334, Nov. 3, 1993

The Examiner finds that Pawelchak discloses a "sponge product comprising hemostatic bioabsorbable cross-linked gelatin foam.... The product comprises ... surface tension modifier including polyoxyethylene derivatives of sorbitan fatty acid esters, such as Tween 60," which are soluble in non-aqueous solvents (Answer 4). The Examiner finds that Pawelchak's product can also comprise glycerin, which is soluble in non-aqueous solvents (*id.* at 4-5).

The Examiner also finds that Pawelchak discloses a "method of making the foam by forming [a] dispersion containing aerated foamed gelatin ... and adding the surfactant and/or glycerin to the dispersion, followed by drying of the dispersion and forming a sponge product" (*id.* at 5). The Examiner reasons that "[a]dding the surfactant and/or glycerin to the dispersion containing foamed aerated gelatin meet[s] the limitation of coating the gelatin with the wetting agent as instantly claimed" (*id.*).

Appellant contends that Pawelchak's product does not anticipate claim 22 because Pawelchak's sponge was formed by the addition of the surfactant during formation of the sponge, rather than afterwards as specified in claim 22, and thus Pawelchak's method results in a different product (Appeal Br. 10-11; Reply Br. 3-4).

We agree with Appellant that the Examiner has not adequately shown that Pawelchak's gelatin-containing sponge product is the same as the gelatin sponge composition of claim 22. Pawelchak discloses a foam sponge product that is prepared by "blending ... gelatin, pectin, and sodium carboxymethylcellulose, adding the mixture to water with agitation so as to form a colloidal dispersion..., foaming the colloidal dispersion..., and then

freeze drying" the foam (Pawelchak, col. 2, l. 67 to col. 3, l. 6). Pawelchak discloses that a "surface tension modifier such as … natural or synthetic surfactants such as lecithin and polyoxyethylene derivatives of sorbitan fatty acid esters such as Tween 60 can be added to the colloidal dispersion to stabilize the gas suspension and enhance the quality of the foam" (*id.* at col. 4, ll. 47-52). Pawelchak also discloses that "[p]lasticizers such as … glycerine can be included within the colloidal dispersion" (*id.* at col. 5, ll. 37-39).

Thus, Pawelchak discloses a gelatin foam product that contains a wetting agent as recited in claim 22, but the wetting agent is added to the colloidal dispersion before the foam is generated rather than applied to a "preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent" as specified in claim 22.

The Examiner reasons that "[a]dding the surfactant to the dispersion containing foamed aerated gelatin as taught by the reference meet[s] the limitation of coating the gelatin with the wetting agent by soaking as instantly claimed by claim 22" (Answer 8).

The Examiner's reasoning is not persuasive. The claim requires "soaking the *preformed* gelatin sponge in a coating solution including the wetting agent and [a] non-aqueous solvent," while Pawelchak discloses adding a surfactant to an aqueous colloidal dispersion of gelatin *before* the gelatin sponge has been formed. We do not agree with the Examiner that Pawelchak discloses the method step recited in claim 22.

The Examiner also reasons that the process limitations of claim 22 do not impart patentability because the claimed product appears to be substantially identical to the prior art product (Answer 9). The Examiner reasons that, in Pawelchak, "the dispersed surface active agent will inevitably [be] present on the surface meeting the claimed limitation of **'coated on at least a substantial portion'**" of the surface of the preformed gelatin sponge (*id.* at 12).

Appellant argues that the process steps of claim 22 impart structural features to the gel foam product that patentably distinguish the claimed product from Pawelchak's gel foam product (Appeal Br. 8-9, Reply Br. 3-4).

We agree with Appellant that the Examiner has not established that one of skill in the art would expect the claimed and prior art products to be the same. Although it may be true that the "Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature," Answer 9-10 (citing *In re Fessmann*, 489 F.2d 742, 744 (CCPA 1974)), the burden shifts to the applicant to prove that the products are not the same only when the PTO has made out a prima facie case that the claimed and prior art products reasonably appear to be the same. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).

Here, although the Examiner asserts that Pawelchak's surfactant would be coated on at least a substantial portion of the surface of its gelatin sponge, Pawelchak anticipates claim 22 only if its coating is structurally the same as a coating applied via the process of claim 22. The Examiner has not provided any evidence or sound technical reasoning to support a conclusion

that Pawelchak's product, with surfactant added before formation of the gel foam, would be structurally the same as a product coated via the process of claim 22, where the preformed gel sponge is soaked in a surfactant-containing solution.

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). That burden has not been met in this case. Thus, we reverse the rejection of independent claim 22 and dependent claims 23-25, 27-30, 32, 33, and 42 under 35 U.S.C. § 102(b).

We also reverse the rejections of claims 26 and 31, which depend from claim 22. For these rejections, the Examiner relies on Pawelchak, as discussed above, and provides a second reference to supply dependent claim limitations. However, as discussed above, the Examiner has not shown that Pawelchak discloses the composition of claim 22. The Examiner also has not explained how the other cited references would have made obvious the limitation that is not disclosed by Pawelchak.

## SUMMARY

We reverse the rejection of claims 22-25, 27-30, 32, 33, and 42 under 35 U.S.C. § 102(b), and we reverse the rejections of claims 26 and 31 under 35 U.S.C. § 103(a).

## REVERSED

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